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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,699	07/06/2001	Thomas J. Brennan	R-173	3947

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EXAMINER
QIAN, CELINE X

ART UNIT	PAPER NUMBER
1636	16

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/900,699	BRENNAN, THOMAS J.	
	Examiner	Art Unit	
	Celine X Qian	1636	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-16 and 20-27* is/are pending in the application.

4a) Of the above claim(s) *11-16 and 20* is/are withdrawn from consideration.

5)☒ Claim(s) *21,22,24 and 25* is/are allowed.

6)☒ Claim(s) *23,26 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/12/02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 11-16 and 20-27 are pending in the application.

Claims 1-10 and 17-19 are cancelled. Claims 11-16 and 20 are withdrawn from consideration for being directed to non-elected subject matter. Newly added claims 21-27 are currently under examination.

This Office Action is in response to the Amendment filed on 2/10/03.

Response to Amendment

The objection of claim 2 is moot in light of Applicants' cancellation of the claims.

The rejection of claims 1-10 and 17-19 under 35 U.S.C.112 1st paragraph is moot in light of Applicants' cancellation of the claims.

The rejection of claims 1-4, 9 and 10 under 35 U.S.C.112 2nd paragraph is moot in light of Applicants' cancellation of the claims.

The rejection of claims 1-10 and 19 under 35 U.S.C.103(a) is moot in light of Applicants' cancellation of the claims.

Newly added claim 23 is rejected under 35 U.S.C.112 1st paragraph for reasons set forth of the record mailed on and further discussed below.

Newly added claims 26 and 27 are rejected under 35 U.S.C.103 (a) for reasons set forth of the record and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a cell isolated from a transgenic mouse having a homozygous disruption of DEZ receptor gene and exhibits the phenotype of decreased agility or coordination, does not reasonably provide enablement for a cell isolated from a transgenic mouse having a heterozygous disruption of DEZ receptor gene. Further, the specification does not support the enablement of a tissue isolated from either a homozygous or heterozygous transgenic mouse. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The newly added claim 23 is rejected for same reasons as applied to now cancelled claims 1-10 and 17-29 that set forth of the record mailed on 11/5/02 (see pages 3-9).

The nature of the invention is a cell or a tissue isolated from a transgenic mouse having a disruption of DEZ receptor gene, wherein when the disruption is homozygous, it exhibits the phenotype of decreased agility or coordination. The claims encompass cell and tissue isolated from both the heterozygous and homozygous transgenic DEZ knockout mouse. The specification teaches that the cell and tissue isolated from the transgenic mouse can be used in assays to screen for agents that ameliorate a phenotype of the transgenic mouse. However, the disclosed phenotype of the homozygous transgenic DEZ knockout mouse is decreased agility or coordination, which can only be determined by a mouse. A tissue isolated from the transgenic mouse would not exhibit this phenotype. The specification fails to teach how to use a tissue isolated from said transgenic mouse to screen for an agent that ameliorate a phenotype of the

transgenic mouse. As such, whether a tissue isolated from the claimed transgenic mouse can be used to screen for agents that ameliorate a phenotype of said mouse is unpredictable. Thus, the specification, in the instant case, is not enabling for a tissue isolated from the transgenic knockout mouse for the screening of agents that ameliorate a phenotype of said mouse. One skilled in the art would have to engage in undue amount of experimentation to use the invention commensurate in scope with these claims.

As discussed in the previous office action, a heterozygous DEZ knockout mouse does not exhibit the same phenotype as the homozygous DEZ knockout mouse. Therefore, a cell isolated from a heterozygous DEZ knockout mouse does not exhibit any phenotype. The specification fails to teach how to use cells comprising a DEZ disruption but without any phenotype. As such, one skilled in the art would have to engage in undue amount of experimentation to use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansour et al (1988, Nature, vol. 336, No. 24, 348-352), in view of Methner et al (1997, BBRC, vol 233, No.2, pages 336-342. IDS) and Murphy et al (1998, Current Opinion in Drug Discovery and Development, vol. 1, No. 2, pages 192-199).

The claims are drawn to a DEZ receptor gene-targeting construct and a murine embryonic stem cell comprising a disruption of endogenous DEZ receptor gene that is produced by said construct. The recitation of "wherein the target construct when...exhibits decreased agility and coordination, relative to a wild-type mouse" defines the intended use of the knockout construct, which does not carry patentable weight.

The teaching of Mansour et al., Methner et al. and Murphy et al. were discussed in detail in the previous office action (see pages 11-13).

It would have been obvious to one of ordinary skill in the art at the time of filing to make a DEZ knockout construct and a murine embryonic stem cell comprising a disruption of DEZ receptor gene by using the knockout construct because of the combined teaching of Mansour et al., Methner et al. and Murphy et al. Contrary to Applicants' assertion that Murphy et al. teaches away from making a DEZ knockout mouse, Murphy et al. provide a good motivation for one of ordinary skill in the art to make such construct, a stem cell comprising DEZ disruption to make a DEZ transgenic knockout mouse to study the physiological and pathophysiological function of DEZ receptor in order to make it a therapeutic target for developing new drugs (see page 192, col.2, 3rd and 4th paragraph). It appears that Applicants have taken a few sentences out the context of the Murphy article, because immediately following the quoted sentences, Murphy et al. state that "despite this caveat, a number of recent studies undertaken with GPCR knockout mice have provided strong support for targeting specific GPCRs for therapeutic development." Such teaching strongly encourages one of ordinary skill of art to make the claimed construct to generate DEZ knockout mice for the purpose of studying its function. The level of skill in the art is high as demonstrated by Mansour et al., who taught a general strategy for making constructs to

knockout any gene in mice. Absent evidence from the contrary, one of ordinary skill in the art would have reasonable expectation of success to make a DEZ receptor knockout construct and transform it to a murine embryonic stem cell. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Claims 21, 22, 24 and 25 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This application contains claims 11-16 and 20 drawn to an invention nonelected with traverse in Paper No. 12. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Anne-marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER

Celine Qian, Ph.D.
April 29, 2003